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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,566	09/03/2003	Yongxing Qiu	CL/V-32635A	5068
1095	7590	08/06/2004	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 430/2 EAST HANOVER, NJ 07936-1080			ZACHARIA, RAMSEY E	
			ART UNIT	PAPER NUMBER
			1773	

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/654,566

**Applicant(s)**

QIU, YONGXING

**Examiner**

Ramsey Zacharia

**Art Unit**

1773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 15-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 2-14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/3/2003</u> . | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-14, drawn to a medical device, classified in class 428, subclass 411.1+.
  - II. Claims 15-20, drawn to a method of producing a medical device, classified in class 427, subclass 331+.
  - III. Claims 21-30, drawn to a method of producing a contact lens, classified in class 264, subclass 239+.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as one in which the non-charged polymeric material is deposited first and the charged polymeric material is then formed on top of the non-charged polymeric material.
3. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as a process that forms a

Art Unit: 1773

medical device other than a contact lens. Alternatively the product can be made by a method comprising applying the biocompatible LbL coating directly to the lens after the lens has been removed from the mold.

4. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different functions.

Invention II acts to form a medical device having a layer of non-charged polymeric material over a layer of charged polymeric material while Invention III acts to form a contact lens that may have a layer of charged polymeric material over a layer of non-charged polymeric material.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Jian Zhou on 04 August 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-14.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Art Unit: 1773

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Information Disclosure Statement***

8. References AD and BL were lined through because they are the same as references AC and AG, respectively, which were initialed and made of record.

9. References AP and AQ were lined through because they failed to comply with 37 CFR 1.98(a)(3) since they are not in English and there is no concise explanation of their relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information. They have been placed in the application file, but the information referred to therein has not been considered.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Fan et al. (U.S. Patent 5,509,899).

Fan et al. teach a device, such as a balloon angioplasty catheter, provided with a biocompatible surface (column 1, lines 43-52). In the embodiment of Example 1, the balloon is coated first with a primer comprising a top coat of polycarboxylic acid (a charged polymeric

Art Unit: 1773

material) which is then coated by polyethylene glycol (a non-charged polymeric material) (column 6, lines 22-63).

***Allowable Subject Matter***

12. Claims 2-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter.

Claims 2-14 are drawn to a medical device comprising a core material and a biocompatible LbL coated non-covalently attached to the core material. The LbL coating comprises at least one charge/non-charge bilayer composed of a layer of charged polymer and a layer of non-charged polymer which is non-covalently bonded to the charged polymer. The charged polymer is a polyanionic polymer of mixture of polyanionic polymers. The non-charged polymer is a homopolymer of copolymer of the vinyl lactam monomer of formula (I) in claim 2.

Fan et al. represents the closest prior art. However, Fan et al. do not teach or fairly suggest the use of a vinyl lactam homopolymer or copolymer coating layer.


***Conclusion***

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramsey Zacharia whose telephone number is (571) 272-1518. The examiner can normally be reached on Monday through Friday from 9 to 5.

Art Unit: 1773

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones, can be reached on (571) 272-1535. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Ramsey Zacharia**  
Primary Examiner  
Tech Center 1700